

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 10 IDAHO OPERATIONS OFFICE

1435 N. Orchard St. Boise, Idaho 83706

December 27, 2010

Barry Koch Special Projects Lead – Mining Monsanto Company P.O. Box 816 Soda Springs, Idaho 83276

Re: Approval of Pre-2004 Biotic Data Validation Reports, prepared for P4 Production LLC by LDC, dated September 8, 2010.

Dear Mr. Koch,

We have completed a limited review of the data validation reports prepared by Laboratory Data Consultants, Inc. (LDC) for P4 Production, LLC (P4). The subject validation reports are specific to the pre-2004 cattle, elk, and bird egg studies. The purpose of the review was to assess the adequacy of LDC's validation process and their qualification of the data. Our review did not assess the quality of the data covered in these validation reports; that is, our review was limited to an evaluation of the validation reports for consistency with the data validation specs and the template developed by P4 in Data Validation Technical Memorandum – Revision 2, dated January 2009, as approved by the A/T. Our review included a limited number of randomly selected validation reports.

Overall, the reviewers (LDC) appear to have appropriately used the above referenced template and carried out a comprehensive review as required by the project specs. The reviewers have flagged the data per the A/T's request; specifically, all samples associated with missing QC data were flagged using a "G" flag to identify missing QC data. A total of 33 missing QC data conditions were identified.

A remaining issue that needs to be tracked is future use of the data, and the potential for misunderstanding by end-users of reported detection limits. There are a large amount of data where the detection limits were not established according to regulatory specifications. Thus, for many samples, the reported detection limit is not comparable to the detection limit that would have been obtained if the analytical laboratory had used the regulatory approach. In risk calculations the reported limits are used quantitatively. The detection limits may also used to screen against regulatory criteria quantitatively. We do not have information on whether the reported laboratory detection limits are more or less conservative than the limits that would have been reported if the laboratory had followed the regulatory procedure. Thus, this creates an uncertainty in decisions that are impacted



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by detection limits. Thus for non-detects, when a statement is made that the results are below the reported limit it is not the same as when the reported limit is obtained by the regulatory procedure.

We are now approving the above referenced reports, and reiterating that future uses of these data must be consistent with findings and limitations identified in the previously approved Data Quality and Usability Report.

Please contact me if you would like to discuss this matter further. I can be reached at 208-378-5763 or electronically at tomten.dave@epa.gov.

Sincerely,

Dave Tomten

Remedial Project Manager

cc: Cary Faulk, MWH (electronic version only)

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